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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,395

03/17/2004

Marc S. Kreidler

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EXAMINER

STEELE, JENNIFER A

ART UNIT

PAPER NUMBER

1794

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,395	Applicant(s) KREIDLER ET AL.	
	Examiner JENNIFER STEELE	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41, 54-61, 63, 68 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 42-53, 62-67, 69-73 and 75-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41, 54-61, 63, 68 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date | 6) <input type="checkbox"/> Other: _____ |

9/23/04; 10/12/04; 7/6/05; 11/30/05; 2/16/06; 8/3/06; 1/26/07.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1-4, 23-25 and 36-39 rejected under 35 U.S.C. 102(b) as being anticipated by Melican et al (US 6,599,323). Melican teaches a biocompatible tissue implant or scaffold for use in the repair and regeneration of diseased or damage tissue (col. 2, lines 9-14). Melican teaches the laminate material is comprised of two layers porous foam with reinforcing mesh wherein the foam pores penetrate the mesh of the reinforcement component and interlock with the reinforcement component (col. 3, lines 46-61).

Regarding claim 2, Melican teaches a support structure disposed between the first and second membrane layers.

As to claims 3 and 4, the laminate fabric of Melican supports cellular attachment and repair (col. 7, lines 12-16).

As to claim 23-25, Melican teaches a knit mesh reinforcing layer that can be comprised of trade name VICRYL which is of PGA/PLA polymer that has a softening point of 80°C (example 1, col. 11, lines 44-67) and teaches tradename PROLENE which is a monofilament polypropylene which would have a softening point of 177°C.

Regarding claims 36-39, Melican teaches a porous first membrane a porous second membrane layer with an open mesh bonding layer that is intended to promote cellular growth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claim 5-13, 26-27, 40-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al (US 6,599,323) in view of Shaw et al (US 5,879,366). Melican differs from the current application and does not teach the thickness of the layers. Shaw teaches a self expanding device for sealing a defect tissue or muscle (col. 1, lines 6-15). Shaw teaches a structure of thin membranes laminated together with an embedded super-elastic wire (col. 2, lines 37-47). Shaw teaches the membranes are of ePTFE cross-laminated to increase membrane strength. Shaw teaches the membrane are each approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001

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inches. While Shaw laminates of 2,4,6, 8 and 10 plies, Shaw teaches a total laminate thickness between 0.0002 to 0.002 which overlaps the range of the claimed invention.

Shaw presents a finding to one of ordinary skill in the art that a biocompatible membrane with layer thicknesses in the range 0.001 to 0.010 inches and less than 0.005 and 0.003 and 0.002 could be employed with a reasonable expectation of success. As Shaw teaches the individual layer thicknesses of the ePTFE film in the range of 0.0002 to 0.002 inches and teaches that a range of plies can be employed, Shaw teaches a laminate that could be no more that 2 or 3 times the first or second membrane layer thicknesses. It further would have been obvious to one of ordinary skill in the art to employ layer thicknesses as taught by Shaw in the invention of Melican motivated to produce a biocompatible laminate for tissue repair.

3. Claim 14-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al (US 6,599,323) in view of Notaras et al (WO 9603091). Melican differs from the current application and does not teach the bonding mesh layer thickness. Notaras teaches mesh materials for surgical use that have a uniform thickness and pore size. Notaras teaches the mesh material thickness may be from 0.05 to 2 mm which is in the range of 0.002 to 0.08 inches and in the ranges of claims 14-17 (pg. 5, lines 5-6).

As to claims 18 and 19, Notaras teaches the importance of pore size and that it may be above 100 micron and preferably between 0.5 to 10 mm which is equal to 0.02 to 0.4 inches (pg. 4, lines 26-36). It would of been obvious to employ a mesh of Notaras motivated to improve the properties of the bio-laminate.

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4. Claim 20-22 and 54 rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al (US 6,599,323) in view of Clubb et al (US 7,323,001). Melican differs from the current application and does not teach a bonding layer the average spacing between adjacent pores and does not teach the percent open area. Chubb teaches an embolic filter with a controlled pore size. Clubb teaches the mesh element has a percent open area of greater than 50%. Clubb teaches the mesh is comprised of minibraids that have a 4 mm diameter or 0.16 inches and 0.001 inches (shown in Fig 3a) which is in the range of claim 22. It would have been obvious to one of ordinary skill in the art to employ a mesh with a surface open area as taught by Clubb motivated to improve the porosity of the bio-laminate.

5. Claim 28-35, 54 -61, 63 and 68 rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al (US 6,599,323) in view of Shaw et al (US 5,879,366) in further view of Hill et al (US 2003/0060871). Melican in view of Shaw teaches a composite membrane wherein the membrane comprises ePTFE. Melican in view of Shaw differs and does not teach the open surface area of the composite membrane. Hill teaches and implantable composite device for the delivery of bioactive agents (ABST). Hill teaches porous ePTFE membranes with porosity sufficient to promote cell endothelialization (ABST). Hill teaches pore sizes of 5-10 microns and greater than 40 microns. Hill teaches differing pore sizes in the outer and inner membranes to improve the properties of the membrane. Hill teaches the space between the node surfaces that is spanned by fibrils is defined as the internodal distance (IND). Hill teaches it is the relative geometry of nodes to fibrils as was the internodal distance that determines the

porosity and permeability of porous PTFE. Hill teaches the IND can be varied to achieve desirable properties and the IND can be varied by controlling the conditions that the PTFE is expanded [0003] and [0004]. Hill does not teach the property of surface open area but it is presumed that the open surface area would be equated to the current application and the porosity and surface area could be optimized to meet the applicants claimed range of 10% to 50%.

As to claims 30-35, Melican in view of Shaw and Hill teach a biocompatible laminate however Melican in view of Shaw and Hill do not teach the property of softening or melting temperature. As Melican, Shaw and Hill teach the same materials and structure as the current application it is reasonable to presume that the softening temperature and melting temperature would be in the claimed range. When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention the examiner has basis for shifting the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112- 2112.02

As to claim 61, 63, 68 and 74, Hill teaches the porous membranes are configured over a frame used for a stent. It would have been obvious to combine the features of the biocompatible laminate of Melican with the membrane porosity of Hill and layer thicknesses of Shaw motivated to improve the properties of a bio-laminate for medical devices.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./
Examiner, Art Unit 1794

/Elizabeth M. Cole/
Primary Examiner, Art Unit 1794

3/27/2008